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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 003,136	11/15/2001	Sharon T. Wong-Madden	NEB-20C2CD3	6015

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NEW ENGLAND BIOLABS, INC.
32 TOZER ROAD
BEVERLY, MA 01915

EXAMINER

FRONDA, CHRISTIAN L.

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/003,136

Applicant(s)
Wong-Madden et al.

Examiner
Christian L. Fronda

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13 is/are pending in the application.
- 4a) Of the above, claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 15, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) ☐ Other

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DETAILED ACTION

Election/Restriction

1. Applicants' election of Group I, claims 7-11, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 7-11 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The claims are directed to any method for modifying any carbohydrate using any glycosidase derived from any *Xanthomonas* strain. The specification, however, only provides a written description for a fucosidase or β -galactosidase obtained from *Xanthomonas manihotis*. The specification does not provide a written description for any method for modifying any carbohydrate using any glycosidase derived from *Xanthomonas*. There is no disclosure of any particular structure to function/activity relationship in the disclosed species of fucosidase or β -galactosidase obtained from *Xanthomonas manihotis*. The specification also fails to describe additional representative species of any glycosidase derived from *Xanthomonas*. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.
5. Claims 7-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for modifying a carbohydrate using a fucosidase or β -galactosidase obtained from *Xanthomonas manihotis*, does not reasonably provide enablement

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for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for modifying any carbohydrate using any glycosidase derived from any *Xanthomonas* strain. The specification provides guidance for a method for modifying any carbohydrate using a fucosidase or β -galactosidase obtained from *Xanthomonas manihotis*. While molecular biological techniques and genetic manipulation are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific glycosidase derived from any *Xanthomonas* strain is lacking. Thus, searching for the specific glycosidase derived from any *Xanthomonas* strain is well outside the realm of routine experimentation and predictability in the art of success in obtaining any glycosidase derived from any *Xanthomonas* strain is extremely low.

The amount of experimentation to obtain any glycosidase derived from any *Xanthomonas* strain is enormous and entails selecting any *Xanthomonas* strain, identifying and purifying any glycosidase, and determining whether the glycosidase can be used in any method to modify any carbohydrate. Since routine experimentation in the art does not include screening vast numbers of *Xanthomonas* strain, where the expectation of obtaining a desired glycosidase is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific identity of the glycosidase. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7 the phrase "one glycosidase derived from *Xanthomonas*" renders the claim

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vague and indefinite because the specific glycosidase claimed in not known and not recited. Claims 9-11 which depend from claim 7 are also rejected because they do not correct the defect of claim 7.

In claim 9 the phrase "biological properties which differ from the glycosidase derived from *Xanthomonas*" renders the claim vague and indefinite because the meaning of the phrase is not known and it is not known what specific biological properties of the modified carbohydrate are to be different from the "glycosidase derived from *Xanthomonas*". Claims 10 and 11 which depend from claim 9 are also rejected because they do not correct the defect of claim 9.

In claim 10, the phrase "altering the immunogenic properties of a glycoprotein" renders the claim vague and indefinite because the specific glycoprotein and its immunogenic properties which are to be altered are not known and not recited in the claim.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

A handwritten signature in black ink, appearing to be 'Jah' or similar, located below the text 'CLF'.